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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,317	11/06/2001	Kazuyuki Miyazawa	SHI-017-USA-PCT	4088

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TOWNSEND & BANTA
c/o PORTFOLIO IP
PO BOX 52050
MINNEAPOLIS, MN 55402

EXAMINER	
EBRAHIM, NABILA G	

ART UNIT	PAPER NUMBER
1618	

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10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/936,317	MIYAZAWA ET AL.	
	Examiner	Art Unit	
	Nabila G. Ebrahim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --.

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-13,16 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 5-13, and 16-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Applicant's remarks and amendments to the claims dated 7/21/07 is acknowledged.

Status of Claims

Claims 1-2, 5-13, and 16-17 are pending in the application.

Claims3-4, 14-15, and 18-20 were cancelled.

Status of Office Action: Final.

Rejections that are not reiterated in the current office action are being withdrawn.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-2, 5-13, and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okura et al. U.S. US 5360624 in view of Hayashi Tadanobu JP4279509 (abstract) (hereinafter Hayashi) and further in view of Murata et al. US Publication 20020006414 (hereinafter Murata).

Okura teaches emulsion-type food in which a part or all of the fat components are substituted by a pulverized curdlan gel. The preparation of the emulsion food is done by gelation and pulverization of the curdlan gel are not significantly disturbed, other raw materials of food can be added before the above gelation or pulverization step as agar, carrageenan, salt of alginic acid, and xanthan gum (col. 3, lines 45+). The particle size after pulverizing is average size of not larger than about 100 microns (col. 3, lines 13+). Note that Okura defines "thermo-reversible gel" used herein means a gel which changes its state in such a manner that it melts at 50.degree. to 80° C and gels at 40° C. or lower and this change of state occurs reversibly. The thermo-reversible gel is prepared, for example, according to one of the following methods:

a. Water is added to curdlan powder, followed by homogenizing with a high speed mixer such as a homogenizer, or a cutter mixer to obtain a uniform suspension. The suspension is heated to about 55 ° C to 80° C, preferably about 60.degree. to 750.degree. C. and then cooled to below 40.degree. C.;

b. Curdlan powder is mixed with hot water at about 55.degree. to 80.degree. C., preferably about 60.degree. to 75° C, and dispersed, followed by cooling to

below about 40° C. The disclosure reads on the amendment in the claims, which recites "allowing the resultant mixture to stand until the temperature of the mixture becomes lower than gelation temperature".

Okura is deficient in the sense that he did not disclose the viscosity recited in the instant claims.

Hayashi teaches obtaining an O/W-type emulsion cosmetic having a specific viscosity and excellent spreadability on the skin and aging stability by compounding specific amounts of xanthan gum and/or locust bean gum and iota-carrageenan. The O/W-type emulsion cosmetic has a static viscosity of 5,000-35,000cp at 25° C and contains (A) 0.2-1.5wt.% (especially 0.3-0.8wt.%) of xanthan gum (a gum having a molecular weight of >=1,000,000 and a structure obtained by bonding two mols of D-mannose and one mol of Na, K or Ca salt of D-glucuronic acid to the side chain of a main chain composed of 1,4-bonded beta-D-glycol, e.g. keltrol) and/or locust bean gum (a neutral polysaccharide composed of galactose and mannose and produced by purifying and pulverizing the albumen of the fruit stone of carob tree, e.g. neosoft L) and (B) 0.2-1.0wt.% (especially 0.4-0.8wt.%) of iota-carrageenan. The cosmetic has new characteristics to exhibit elasticity and semifluidity in stationary state.

It would have been obvious to one of ordinary skills in the art to adjust the viscosity in the method disclosed by Okura because Hayashi teaches that the composition disclosed has new characteristics to exhibit elasticity and semifluidity in stationary state.

The two references do not teach delivering an active agent in the microgel.

Murata teaches an external composition for a skin cosmetic that can be a whitening agent [0023], an anti-inflammatory agent can be added [0074] or Vitamin E [0085]. The composition comprises carrageenan, alginate [0085], agar [see table 1] and polyacrylate [0082].

Since Murata used similar ingredients such as carrageenan, and polyacrylate, it would have been obvious to one of ordinary skills in the art at the time the invention was made to add an active agent as a vitamin, anti-inflammatory, or whitening agent to the particles made by Okura and adjust the viscosity according to Hayashi. The skilled artisan would be motivated by expanding the use of the prepared particles for food consuming disclosed by Okura. The expected result would be a microgel that is produced by dissolving a hydrophilic gelling agent in water, allowing it to gel and then pulverizing. Into a specific particle size.

The amendments to the claims would not affect the rejection since the heating step is disclosed by Okura and the viscosity was disclosed by Hayashi, the properties gained by using this specific viscosity is an inherent property.

Response to Arguments

4. Applicant's arguments filed 7/21/07 have been fully considered but they are not persuasive. Applicant argues that:

- The gel disclosed in Okura contains curdlan as the mandatory (principle) component, and even if agar or carrageenan, for example, is added to the mixture, agar or carrageenan are simply additional optional elements of the curdlan-derived gel. Further, Okura, et al. teaches that the amount of same must be limited, such that "they

are used in such amounts that sufficient swelling of curdlan is not disturbed when they are added before the gelation step of curdlan" (see column 4, lines 3-5).

To respond: curdlan is an equivalent alternative to xanthan gum, succinoglycan polyacrylic acid, polyethylene glycol, polyacrylamide, and a polyalkylacrylamide/polyacrylamide copolymer. It is clear that any of these alternative can carry out the invention. This is disclosed in the instant application in paragraph [0011] under the title "BEST MODE FOR CARRYING OUT THE INVENTION".

- The microgel of the present invention is produced by the process of claim 1, wherein, in the first step, both the hydrophilic compound, as well as a viscosity increasing compound incapable of forming a gel selected from xanthan gum, succinoglycan, polyacrylic acid, polyethylene glycol, polyacrylamide, and/or a polyalkylacrylamide/polyacrylamide copolymer, is dissolved in the aqueous solvent. Importantly, carrageenan and curdlan, as called for by Okura, et al., are not included in the hydrophilic compound now claimed herein in base claim 1.

To respond: As understood from Applicant arguments, the first step of claim 1 requires a hydrophilic compound capable of forming a gel **and** a viscosity increasing compound incapable of forming a gel selected from ....etc. This is not correct, first step claim 1 requires only **a hydrophilic gelling material, an aqueous solvent and heat**. It is noted that Okura teaches in example 1 curdlan (which is an equivalent to the gelling ingredients recited in amended claim 1) and xanthan gum a solvent and heat. A compound and its properties are not separable, the prior art clearly uses same

ingredients. It is not necessarily that the prior art recognizes each and every advantage that a compound can accrue from the use of the particular ingredient.

- Okura, et al. fail to teach or suggest that the microgel thereof is produced by pulverizing a gel comprised solely of agar, gelatin, gellan gum and/or alginic acid, or a gel and fails to teach or suggest that inclusion of the microgel in an external composition.

To respond: Again curdlan is an alternative to agar, gelatin, gellan gum and/or alginic acid, this is disclosed in the instant disclosure [0011]. The use of composition containing gelling materials in external compositions was known by art evidenced by Hayashi and Murata

- Hayashi fails to teach or suggest that such a microgel has excellent viscosity increasing properties, and, all external composition containing such microgel would have a high viscosity, such as 50,000 mPa.s or 400,000 mPa's, provides good sensation during use, and exhibits excellent long-tema stability.

To respond: Hayashi teaches a cosmetic formulation having viscosity of 5,000-35,000cp at 25° C and contains (A) 0.2-1.5wt.% (especially 0.3-0.8wt.%) of xanthan gum. In addition, instant claims 6 and 17 recite a microgel has a viscosity of 2,000-1,000,000 mPa-s at 25°C, this is a very broad range that encompass the values recited by Hayashi. It is also obvious that the composition of Hayashi would have the same nonsticky property even if it was not literally disclosed in the abstract.

- "agar", as described in Table 1, appears to refer to a culture medium. Thus, it is believed that Murata, et al. does not teach or suggest that the external composition can contain agar, or a microgel produced by pulverizing a gel of agar.

To respond: Murata did not disclose agar only , Murata teaches that in other citations. In addition, Murata discloses that other materials that can be included in the external composition for skin of the invention include, carrageenan, alginate, alginic acid propylene glycol ester [0085]; this is the same paragraph cited in the rejection.

- Murata, et al. fail to teach or suggest that such a microgel has excellent viscosity increasing properties, and an external composition containing such microgel has high viscosity, provides good sensation during rise, and exhibits excellent long-term stability.

To respond: Murata was introduced to the rejection to obviate the use of other ingredients such as vitamins and anti-inflammatory agents, the viscosity range that is within the range disclosed by the instant claims was disclosed by Hayashi and the good sensation and long-term stability are inherent properties for the same compounds used by Okura.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim
9/30/07

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER